

AGENDA
DEPARTMENT OF HEALTH
BOARD OF PHARMACY
STERILE COMPOUNDING COMMITTEE
October 18, 2016

Committee Members:

Michele Weizer, PharmD, BCPS, Chair

Mark Mikhael, PharmD

Debra Glass, BPharm

Board Counsel:

David Flynn, Assistant Attorney General

Lawrence Harris, Assistant Attorney General

Board Staff:

Allison Dudley, Executive Director

Bianca Bell, Program Operations Administrator

Alexandra Meredith, Regulatory Supervisor

PLEASE TURN OFF ALL CELL PHONES, PAGERS AND BEEPERS DURING THE MEETING. THANK YOU.

Tuesday October 18, 2016; Immediately Following Rules Committee

1. Update from FDA Intergovernmental Meeting on Sterile Compounding

2. Rules Update

Rule 64B16-27.797, the Standards of Practice for Compounding Sterile Products

Rule 64B16-28.802, Special Sterile Compounding Permits

3. Rule 64B16-28.905, Nonresident Sterile Compounding Permit Inspections; Approved Inspection Entities

- Discussion re Inspection Entities for Outsourcing Facilities

4. USP 731 – Loss on Drying

5. FDA Guidance Documents (Informational)

6. Future meetings

7. New business/old business

8. Public Comment

Participants in this public meeting should be aware that these proceedings are being recorded.